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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,085	06/01/2005	Michael L. King	PU4927USW	8241
23347	7590	01/24/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER MITCHELL, TEENA KAY	
			ART UNIT 3771	PAPER NUMBER
			NOTIFICATION DATE 01/24/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/537,085	<b>Applicant(s)</b> KING, MICHAEL L.	
	<b>Examiner</b> Teena Mitchell	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/7/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/07/07 has been entered.

### ***Allowable Subject Matter***

The indicated allowability of claims 1-34 is withdrawn in view of the newly discovered reference(s) to Mono et.al. (4,292,966). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-13, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mono et.al. (4,292,966).

Regarding claim 1, Mono discloses a container (8) having a pharmaceutical formulation comprising at least one medicament (BACKGROUND ART) present therein; and a mouthpiece (1, 5) configured for oral engagement with a patient

and in communication with said container (Fig. 1), the mouthpiece having an inner surface and an outer surface (Figs. 3, 4); wherein the outer surface of the mouthpiece contains at least one longitudinally-extending disuniformity (note illustration of Fig. 4 below) such that when the patient orally engages the mouthpiece at least one void cavity space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient (Figs. 1-4).

Regarding claim 2, Mono discloses wherein the at least one longitudinally-extending disuniformity is selected from the group consisting of at least one protrusion, at least one indentation, at least one opening in the outer surface of the mouthpiece (Note Fig. 4 below).

Regarding claim 3, Mono discloses wherein at least one longitudinally-extending disuniformity comprises a plurality of protrusions (Figs. 3, 4).

Regarding claim 4, Mono discloses wherein the plurality of protrusions are equidistant from one another (Figs. 3, 4).

Regarding claim 5, Mono discloses wherein the plurality of protrusions are present opposite to each other along respective sides of the mouthpiece (Figs. 3, 4).

Regarding claim 7, Mono discloses wherein said at least one protrusion is present as one protrusion (Figs. 3, 4).

Regarding claim 8, Mono discloses wherein the said at least one longitudinally-extending disuniformity comprises a plurality of indentations (Figs. 3, 4).

Regarding claim 9, Mono discloses wherein the plurality of indentations comprise two indentations present opposite to each other along opposing sides of the mouthpiece (Figs. 3, 4).

Regarding claim 10, Mono discloses wherein the longitudinally-extending disuniformity is present as at least one opening (Figs. 3, 4).

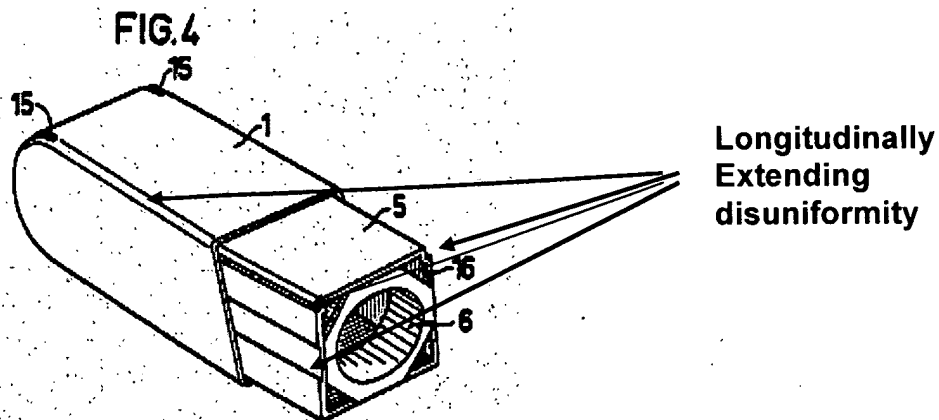
Regarding claim 11, Mono discloses wherein at least one opening comprises a plurality of openings (Figs. 3, 4).

Regarding claim 12, Mono discloses wherein the plurality of openings comprises two openings each present opposite to each other on opposing sides of the mouthpiece (Figs. 3, 4).

Regarding claim 13, Mono discloses wherein the pharmaceutical formulation comprises at least one medicament (BACKGROUND ART).

Regarding claim 27, note rejections of claims 1, 2, 8

Regarding claim 28, Mono discloses activating the inhaler to deliver the at least one medicament to the patient (Col. 2, lines 65-68).



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mono et.al. (4,292,966).

Regarding claim 6, Mono discloses the claimed invention except for the protrusions present throughout the outer surface of the mouthpiece. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the protrusions present throughout the outer surface of the mouthpiece, since it has been held that rearranging of parts of an invention involves only routine skill in the art and if protrusions are present throughout the outer surface the user would be

able to receive more of the medicament as they inhale in as more air and medicament would be inhaled. In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

**Claims 14-26 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mono et.al. (4,292,966) in view of Rand (6,474,331).**

Regarding claims 14-26 and 29-34 Mono discloses the claimed invention except for the specific medicaments. Rand in an inhaler teaches the limitations of the claimed medicaments, therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the claimed medicaments based upon the teachings of Rand because such medicaments are well-known in the respiratory art (Col. 9, lines 40-67 and Col. 10, lines 1-20).

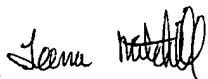
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Teena Mitchell  
Primary Examiner  
Art Unit 3771  
January 21, 2008

  
TKM